

LISTING OF CLAIMS

None of the claims have been amended in this response. This Listing Of Claims is provided for the convenience of the Examiner.

1-24. (Cancelled)

25. (Previously presented) A needleless valve comprising:

a housing comprising a proximal end, a distal end, and an internal cavity with a first region positioned near the proximal end with a first horizontal cross-sectional width, a second region with a second horizontal cross-sectional width larger than the first horizontal cross-sectional width, the second region positioned in a distal direction from the first region, the proximal end configured to receive a delivery end of a medical implement for transferring fluid through the delivery end;

a flexible element with a proximal end and a distal end, the flexible element positioned within the internal cavity of the housing for controlling a flow of fluid through a fluid pathway through the valve, the flexible element comprising a first height in a first position and a second height in a second position, the first height being greater than the second height, the proximal end of the flexible element configured to move in a distal direction from the first position to the second position upon insertion of the delivery end of the medical implement into the proximal end of the housing, the proximal end of the flexible element configured to move in a proximal direction in the cavity to the first position upon removal of the delivery end from the proximal end of the housing, the flexible element comprising an orifice at its proximal end to facilitate fluid flow therethrough, wherein the proximal end of the flexible element, when in the first position, is generally flush with the proximal end of the housing, has at least a portion that contacts the housing in a region at or near the proximal end of the housing, and presents an impediment to entry of bacteria into the fluid pathway without requiring a covering for the housing; and

a spike with a proximal end and a distal end, the distal end disposed at or near a distal end of the cavity in the housing, the spike having a hole at the proximal end thereof, wherein the distal end of the flexible element is positioned in close radial proximity with a distal section of the spike.

26. (Previously presented) The valve of Claim 25, wherein the spike facilitates a flow of fluid in a distal direction from the inside of the flexible element to a region outside of the flexible element.
27. (Previously presented) The valve of Claim 25, wherein the spike assists in supporting the flexible element within the cavity of the housing.
28. (Previously presented) The valve of Claim 25, wherein the spike assists in centering the flexible element within the cavity of the housing.
29. (Previously presented) The valve of Claim 25, wherein the proximal end of the spike has a pointed tip.
30. (Previously presented) The valve of Claim 25, wherein the flexible element in its first position completely blocks the flow of fluid through the valve.
31. (Previously presented) The valve of Claim 25, wherein the flexible element further comprises a cap portion.
32. (Previously presented) The valve of Claim 31, wherein the orifice is positioned in the cap portion of the flexible element.
33. (Previously presented) The valve of Claim 32, wherein the shape of the cap portion is adapted to facilitate closure of the orifice when the flexible element is in the first position.
34. (Previously presented) The valve of Claim 32, wherein the cap portion has a generally circular cross-section when the flexible element is in the first position.
35. (Previously presented) The valve of Claim 25, wherein the internal cavity of the housing further comprises a third region with a third horizontal cross-sectional width larger than the second horizontal cross-sectional width, the third region positioned in a distal direction from the second region.
36. (Previously presented) The valve of Claim 35, wherein the first, second, and third cross-sectional widths are diameters spanning substantially circular cross-sections of the internal cavity.
37. (Previously presented) The valve of Claim 36, wherein at least a portion of the housing in a region of the internal cavity between the first region and the third region has a tapered interior surface.

38. (Previously presented) The valve of Claim 25, wherein the valve provides substantially linear fluid flow from the medical implement through the valve.
39. (Previously presented) The valve of Claim 25, wherein the orifice is made before the flexible element is used to transfer fluid therethrough.
40. (Previously presented) The valve of Claim 25, wherein at least a portion of the flexible element is corrugated.
41. (Previously presented) The valve of Claim 25, wherein at least a portion of an outer surface of the flexible element is an imperforate bellows.
42. (Previously presented) The valve of Claim 25, wherein the spike is formed of plastic.
43. (Previously presented) The valve of Claim 42, wherein the distal end of the spike is unitary with the housing.
44. (Previously presented) The valve of Claim 25, wherein the flexible element moves between the first and second positions in an accordion-like fashion.
45. (Previously presented) The valve of Claim 25, wherein the proximal end of the spike is located within the cavity in a distal direction from the proximal end of the housing.
46. (Previously presented) The valve of Claim 45, wherein the proximal end of the spike is positioned approximately 0.1" to 0.525" from the proximal end of the housing.
47. (Previously presented) The valve of Claim 46, wherein the proximal end of the spike is positioned approximately 0.525" from the proximal end of the housing.
48. (Previously presented) The valve of Claim 25, wherein a horizontal radius of the spike is greater at the distal end of the spike than at the proximal end of the spike.
49. (Previously presented) The valve of Claim 25, wherein the housing further comprises a fluid conduit extending distally from the internal cavity in the housing and a skirt surrounding the fluid conduit.
50. (Previously presented) The valve of Claim 49, wherein the skirt further comprises internal and external surfaces and at least one thread positioned on the internal surface for detachably connecting the valve to a second medical implement.
51. (Previously presented) The valve of Claim 25, wherein the housing is comprised of multiple, separately molded plastic structures configured to be joined together to define the internal cavity of the housing.

52. (Previously presented) The valve of Claim 25, wherein the flexible element is made of a compound comprising silicone rubber.
53. (Previously presented) The valve of Claim 29, wherein the pointed tip of the spike penetrates the flexible element when the flexible element is in the second position.
54. (Previously presented) The valve of Claim 25, wherein the spike penetrates the orifice when the flexible element is in the second position to allow the flow of fluid therethrough.
55. (Previously presented) The valve of Claim 25, wherein the spike is tapered.
56. (Previously presented) The valve of Claim 25, wherein the portion of the flexible element that contacts the housing in the region at or near the proximal end of the housing fills essentially completely an opening in the proximal end of the housing in a horizontal cross-sectional dimension.
57. (Previously presented) A medical valve comprising:
- a housing comprising a proximal end, a distal end, an internal cavity, and an external surface with threads on at least a portion thereof, the proximal end comprising an opening configured to receive a delivery end of a medical implement for transferring fluid through the delivery end;
 - a flexible element positioned within the internal cavity of the housing for controlling a flow of fluid through a fluid pathway through the valve, the flexible element comprising a proximal end and a distal end, the flexible element configured to be in a fluid-impedance position and a fluid-flow position, the flexible element configured to move from the fluid-impedance position to the fluid-flow position when the delivery end of the medical implement is inserted into the opening and exerts a distally directed force on the proximal end of the flexible element to compress the flexible element, the flexible element configured to move proximally in the cavity, returning to the fluid-impedance position upon removal of the delivery end of the medical implement from the opening, the flexible element in the fluid-impedance position comprising a portion that contacts the housing in a region at or near the proximal end of the housing, and an orifice at the proximal end to facilitate fluid flow therethrough, wherein the proximal end of the flexible element is generally flush with the proximal end of the housing in the fluid-

impedance position, the flexible element comprising a series of closely spaced, substantially horizontal grooves to facilitate axial compression of the flexible element; and

a plastic tube with a proximal end and a distal end, the distal end disposed at or near the distal end of the cavity in the housing, the tube facilitating the flow of fluid through the valve, wherein the distal end of the flexible element is positioned in close radial proximity with a distal section of the tube.

58. (Previously presented) The valve of Claim 57, wherein the internal cavity in the housing comprises a first region positioned near the proximal end of the housing with a first horizontal cross-sectional width, and a second region with a second horizontal cross-sectional width larger than the first horizontal cross-sectional width, the second region positioned in a distal direction from the first region.
59. (Previously presented) The valve of Claim 57, wherein the flexible element in the fluid-impedance position completely blocks flow of fluid through the valve.
60. (Previously presented) The valve of Claim 57, wherein the flexible element further comprises a cap portion.
61. (Previously presented) The valve of Claim 60, wherein the orifice is positioned in the cap portion of the flexible element.
62. (Previously presented) The valve of Claim 61, wherein the shape of the cap portion is adapted to facilitate closure of the orifice when the flexible element is in the fluid-impedance position.
63. (Previously presented) The valve of Claim 61, wherein the cap portion has a generally circular cross-section when the flexible element is in the fluid-impedance position.
64. (Previously presented) The valve of Claim 58, wherein the internal cavity of the housing further comprises a third region with a third horizontal cross-sectional width larger than the second horizontal cross-sectional width, the third region positioned in a distal direction from the second region.

65. (Previously presented) The valve of Claim 64, wherein the first, second, and third cross-sectional widths are diameters spanning substantially circular cross-sections of the internal cavity.
66. (Previously presented) The valve of Claim 65, wherein at least a portion of the housing in a region of the internal cavity between the first region and the third region has a tapered interior surface.
67. (Previously presented) The valve of Claim 57, wherein the valve provides substantially linear fluid flow from the medical implement through the valve.
68. (Previously presented) The valve of Claim 57, wherein the orifice is made before the flexible element is used to transfer fluid therethrough.
69. (Previously presented) The valve of Claim 57, wherein at least a portion of the flexible element is corrugated.
70. (Previously presented) The valve of Claim 57, wherein at least a portion of an outer surface of the flexible element is an imperforate bellows.
71. (Previously presented) The valve of Claim 57, wherein the distal end of the tube is unitary with the housing.
72. (Previously presented) The valve of Claim 57, wherein the flexible element moves between the fluid-impedance and the fluid-flow positions in an accordion-like fashion.
73. (Previously presented) The valve of Claim 57, wherein the proximal end of the tube is located within the cavity in a distal direction from the proximal end of the housing.
74. (Previously presented) The valve of Claim 73, wherein the proximal end of the tube is positioned approximately 0.1" to 0.525" from the proximal end of the housing.
75. (Previously presented) The valve of Claim 74, wherein the proximal end of the tube is positioned approximately 0.525" from the proximal end of the housing.
76. (Previously presented) The valve of Claim 57, wherein a horizontal radius of the tube is greater at the distal end of the tube than at the proximal end of the tube.
77. (Previously presented) The valve of Claim 57, wherein the housing further comprises a fluid conduit extending distally from the internal cavity in the housing and a skirt surrounding the fluid conduit.

78. (Previously presented) The valve of Claim 77, wherein the skirt further comprises internal and external surfaces and at least one thread positioned on the internal surface for detachably connecting the valve to a second medical implement.
79. (Previously presented) The valve of Claim 57, wherein the housing is comprised of multiple, separately molded plastic structures configured to be joined to define the internal cavity of the housing.
80. (Previously presented) The valve of Claim 57, wherein the flexible element is made of a compound comprising silicone rubber.
81. (Previously presented) The valve of Claim 57, wherein the tube penetrates the flexible element when the flexible element is in the fluid-flow position.
82. (Previously presented) The valve of Claim 57, wherein the tube penetrates the orifice when the flexible element is in the fluid-flow position.
83. (Previously presented) The valve of Claim 57, wherein the tube is tapered.
84. (Previously presented) The valve of Claim 57, wherein the portion of the flexible element that contacts the housing in the region at or near the proximal end of the housing fills essentially completely the opening in a horizontal cross-sectional dimension.
85. (Previously presented) A needleless valve comprising:
- a housing comprising a proximal end, a distal end, and an internal cavity with a first region with a first cross-sectional width positioned near the proximal end, a second region with a second cross-sectional width larger than the first cross-sectional width and positioned in a distal direction from the first region, the proximal end having an opening, and a region of the housing adjacent the opening comprising a tapered wall configured to receive a standard-sized luer for transferring fluid;
 - a flexible element with a proximal end and a distal end, the flexible element positioned within the internal cavity of the housing for controlling a flow of fluid through a fluid pathway through the housing, the flexible element comprising a first height in a substantially closed position and a second height in a substantially open position, the first height being greater than the second height, the proximal end of the flexible element configured to move in a distal direction from the substantially closed position to the

substantially open position upon insertion of a delivery end of a medical implement into the opening, the proximal end of the flexible element configured to move in a proximal direction in the cavity to the substantially closed position upon removal of the delivery end of the medical implement from the opening, the flexible element in the substantially closed position comprising a portion that contacts the housing in a region at or near the proximal end of the housing, and the flexible element further comprising a series of closely spaced, substantially horizontal grooves to facilitate axial compression, and an orifice at the proximal end to permit fluid flow therethrough; and

a rigid element with a proximal end, a distal end, and a fluid pathway therein, the distal end of the rigid member disposed at or near the distal end of the cavity, the rigid member facilitating the flow of fluid through the valve, wherein the distal end of the flexible element is positioned in close radial proximity with a distal section of the rigid element.

86. (Previously presented) The valve of Claim 85, wherein the rigid element is a spike.

87. (Previously presented) The valve of Claim 86, wherein the spike has a pointed proximal tip.

88. (Previously presented) The valve of Claim 85, wherein the rigid element is a tube.

89. (Previously presented) The valve of Claim 85, wherein the valve is adapted to form a substantially fluid-tight seal between the delivery end of the medical implement and the flexible element during fluid transfer.

90. (Previously presented) The valve of Claim 85, wherein the internal cavity of the housing further comprises a third region with a third cross-sectional width larger than the second cross-sectional width, the third region positioned in a distal direction from the second region.

91. (Previously presented) The valve of Claim 85, wherein the flexible element in the substantially closed position completely blocks flow of fluid through the valve.

92. (Previously presented) The valve of Claim 85, wherein the flexible element further comprises a cap portion.

93. (Previously presented) The valve of Claim 92, wherein the orifice is positioned in the cap portion of the flexible element.

94. (Previously presented) The valve of Claim 93, wherein the shape of the cap portion is adapted to facilitate closure of the orifice in the substantially closed position of the flexible element.
95. (Previously presented) The valve of Claim 85, wherein the cap portion has a generally circular cross-section when the flexible element is in the substantially closed position.
96. (Previously presented) The valve of Claim 90, wherein the first, second, and third cross-sectional widths are diameters spanning substantially circular cross-sections of the internal cavity.
97. (Previously presented) The valve of Claim 90, wherein at least a portion of the internal cavity between the first region and the third region has a tapered interior surface.
98. (Previously presented) The valve of Claim 89, wherein the valve provides substantially linear fluid flow from the medical implement through the valve.
99. (Previously presented) The valve of Claim 85, wherein the orifice is made before the flexible element is used to transfer fluid.
100. (Previously presented) The valve of Claim 85, wherein the flexible element is corrugated.
101. (Previously presented) The valve of Claim 85, wherein the flexible element comprises a resilient, imperforate bellows.
102. (Previously presented) The valve of Claim 85, wherein the rigid element is formed of plastic.
103. (Previously presented) The valve of Claim 85, wherein the distal end of the rigid element is unitary with the housing.
104. (Previously presented) The valve of Claim 85, wherein the flexible element moves between the substantially closed and substantially open positions in an accordion-like fashion.
105. (Previously presented) The valve of Claim 85, wherein the proximal end of the rigid element is located within the cavity in a distal direction from the proximal end of the housing.

106. (Previously presented) The valve of Claim 105, wherein the proximal end of the rigid element is positioned approximately 0.1" to 0.525" from the proximal end of the housing.
107. (Previously presented) The valve of Claim 106, wherein the proximal end of the rigid element is positioned approximately 0.525" from the proximal end of the housing.
108. (Previously presented) The valve of Claim 85, wherein a horizontal radius of the rigid element is greater at the distal end than at the proximal end.
109. (Previously presented) The valve of Claim 85, wherein the housing further comprises a tube extending distally from the internal cavity in the housing and a skirt surrounding the tube.
110. (Previously presented) The valve of Claim 109, wherein the skirt further comprises internal and external surfaces and a thread positioned on the internal surface for detachably connecting the valve to a second medical implement.
111. (Previously presented) The valve of Claim 110, wherein the thread is a screw thread.
112. (Previously presented) The valve of Claim 85, wherein the housing is comprised of multiple, separately molded plastic structures configured to be joined to define the internal cavity of the housing.
113. (Previously presented) The valve of Claim 85, wherein the flexible element is made of a compound comprising silicone rubber.
114. (Previously presented) The valve of Claim 85, wherein the tube penetrates the orifice when the flexible element is in the substantially open position to allow the flow of fluid.
115. (Previously presented) The valve of Claim 85, wherein the orifice is precut.
116. (Previously presented) The valve of Claim 85, wherein the tube is tapered.
117. (Previously presented) The valve of Claim 85, wherein a portion of the flexible element in the substantially closed position fills essentially completely a horizontal cross-sectional dimension of the opening.

Appl. No. : **10/630,131**
Filed : **July 30, 2003**

118. (Previously presented) The valve of Claim 85, wherein the proximal end of the flexible element in the substantially closed position is substantially flush with the proximal end of the housing.
119. (Previously presented) The valve of Claim 85, wherein a portion of the flexible element in the substantially closed position contacts the housing around substantially the entire perimeter of the opening.